USEFULNESS OF THE FOUR SCORE COMA SCALE IN CHILDREN ADMITTED AT AN INTENSIVE CARE UNIT OF A REFERRAL CENTRE

Dissertation submitted to

THE TAMIL NADU DR. M.G.R. MEDICAL UNIVERSITY

In partial fulfilment of the regulations

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M.D DEGREE (PAEDIATRICS) BRANCH VII

INSTITUTE OF CHILD HEALTH AND

HOSPITAL FOR CHILDREN

MADRAS MEDICAL COLLEGE

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CERTIFICATE

This is to certify that the dissertation titled, **"Usefulness of the FOUR score coma scale in children admitted at an Intensive Care Unit of a referral centre"** submitted by **Dr.V.Vairavasundaram,** to the Faculty of Paediatrics, The Tamil Nadu Dr.M.G.R. Medical University, Chennai, in partial fulfilment of the requirements for the award of M.D. Degree (Paediatrics) is a bonafide research work carried out by him under our direct supervision and guidance, during the academic year 2010-2012.

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DECLARATION

I, **Dr.V.Vairavasundaram**, solemnly declare that the dissertation titled **"Usefulness of the FOUR score coma scale in children admitted at an Intensive Care Unit of a referral centre"** has been prepared by me.

This is submitted to The Tamil Nadu Dr.M.G.R.Medical University, Chennai in partial fulfillment of the rules and regulations for the M.D. Degree Examination in Paediatrics.

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CERTIFICATE OF APPROVAL

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Dear Dr. V. Vairavasundaram

The Institutional Ethics Committee of Madras Medical College reviewed and discussed your application for approval of the proposal entitled " Usefulness of the four score coma scale in children admitted at an intensive care unit of a referral center" No. 14032011.

The Following Members of Ethics committee were present in the Meeting held on 17.03.2011 conducted at Madras Medical College, Chennai -3

1. Prof. S.K. Rajan MD	-- Chairperson
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We approve the proposal to be conducted in its presented form.

Sd/ chairman & Other Members

The Institutional Ethics committee expects to be informed about the progress of the study and SAE occurring in the course of the study , any changes in the protocol and patient information / informed consent and asks to be provided a copy of the final report.

Member Secretary, Ethics Committee

SPECIAL ACKNOWLEDGEMENT

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CONTENTS

INTRODUCTION

Consciousness is the state of awareness of both one's own self and his environment. A child who has a normal state of consciousness can be awakened and also aware of what is happening in and around her or himself. Altered level of consciousness is the impairment of the ability to maintain awareness of self and environment, and respond to environmental stimuli. Understanding of normal level of consciousness is necessary for the evaluation of abnormalities in a child's behaviour.

ALOC usually begins with reduced awareness of one's self, followed by reduction in awareness of the environment, and finally by inability to aroused. The opposite of consciousness is coma, a state in which a person is unresponsive to all stimuli, including pain. Although consciousness and coma represents the extremes of mental status, there are many abnormal states of consciousness along that spectrum that may, at times, blunt imperceptibility into one another.

Confusion occurs when there is a loss of clear thinking, usually manifested by impairment of cognitive abilities and decision making. Disorientation often accompanies confusion. In general, disorientation

to time occurs first, followed by disorientation to place, and then by deficiency in short term memory. Loss of recognition of one's self is a latter finding. In delirium, there is a succession of confused and unconnected ideas. Delirious children often have extreme mental and motor excitement, so they become disoriented, fearful, irritable, offensive, or agitated.

A mildly depressed level of consciousness may be classed as lethargic;[1] child in this state will be aroused with little difficulty. Child who is obtunded has a more depressed state of consciousness and can't be fully aroused.[1,2] Those who are unable to be aroused from a sleep like- state are called stuporous.[1,2] Coma is the inability to make an any purposeful response.

A persistent vegetative state and coma often are confusing. In both the vegetative state and coma, there is no evidence of self-awareness (no response to communication and purposeful movements) or communication (either verbal or by gestures). However, in vegetative state, the child's eyes may open spontaneously, giving the appearance of a state of arousal as opposed to that of coma, in which the eyes are always closed.

Epidemiology :

An altered level of consciousness in children has many causes, with fundamental differentiation being between structural and non-structural. Although these disorders can occur at any age, certain conditions are more prevalent at specific ages.

Nontraumatic coma has a bimodal distribution, being most common in infants and toddlers and having another small peak in adolescence.

Infection either of the brain (encephalitis), meninges (meningitis), or both is the most common cause of altered level of consciousness, accounting for more than one third of nontraumatic cases.

Congenital malformations, especially those of the central nervous system, typically present in early postnatal period, but complications from surgical correction of such problems (e.g. Ventriculo peritoneal shunt) may occur at any age.

Diabetic ketoacidosis, the most common metabolic disorder presenting with alteration of consciousness, can occur at any age but more common in adolescence.

Inborn errors of metabolism, including those that present with electrolyte and glucose abnormalities typically present in infancy. Prolonged seizures, anticonvulsive therapy, and the postictal state also can alter the level of consciousness.

Toxic exposure or ingestion is most common in childhood and adolescence. A toddler has the ability to explore the environment but does not yet have the cognitive ability to know that ingesting pills may be harmful. Many medications (especially those targeted for use in paediatrics) are brightly coloured and tasty, creating an inviting stimulus for accidental ingestion.

Commonly ingested agents that cause an altered level of consciousness are amphetamines, anticholinergics, anticonvulsants, barbiturates, benzodiazepines, clonidine, cocaine, ethanol, haloperidol, narcotics, phenothiazines, salicylates, selective serotonin reuptake inhibitors (SSRIs), tricyclic antidepressants.

Ingestion by adolescents usually is intentional and typically involves over- the- counter medication (eg, acetaminophen, ibuprofen) or psychotropic drugs such as antidepressants.

Although the overall incidence of traumatic and nontraumatic coma is similar, the rate of traumatic injury trends to increase throughout childhood. Trauma, especially head trauma, can cause intra cerebral, epidural, or subdural bleeding, leading to cerebral dysfunction either by primary neuronal damage or the effects of cerebral herniation or brainstem compression.

Intentional trauma (child abuse) always should be considered in any infant presenting with altered level of consciousness.

Pathophysiology of coma:

The clinician can determine the child's state of awareness by the child's behaviour. The content of a child's behaviour can be inferred by his or her actions and appearance. Normal behaviour requires appropriate cognition and affect, enabling children to perceive the relationship between themselves and their environment. This component of behaviour is controlled by the cerebral hemispheres.

In a typical day, the body goes through a normal cycling of alertness. From a state of wakefulness, it is normal to become drowsy and, eventually, to fall asleep. At some point during sleep (or even during drowsiness), external stimuli are processed through sensory inputs to increase awareness and cause one to be more awake. This cycling of behaviour is modulated predominantly by the ascending reticular activating system (ARAS), a core brainstem structure that often is considered the "sleep centre". Thus, normal behaviour can be thought of as a combination of appropriate "content" and arousal.

A useful method of approaching altered level of consciousness is the bulb - switch analogy. Consider the content of behaviour (controlled by the cerebral hemispheres) to be a light bulb and the arousal component (controlled by the ARAS) to be light switch. For the bulb to be lit (at a normal level of consciousness), the bulb has to be functional and switch on. There are three possibilities if the bulb is not lit (altered level of consciousness): a defect in the bulb itself (diffuse dysfunction of cerebral hemispheres), a defect in the switch (a localized abnormality of the ARAS), or defect in both the bulb and the switch (global CNS dysfunction).

The ascending reticular activating system is located in the vicinity of several brainstem reflexes, including pupillary light reflexes (2^{nd} & 3^{rd} cranial nerves) and reflex eye movements (3^{rd}, 4^{th}, 8^{th} cranial nerves and medial longitudinal fasciculus). Thus preservation of these reflexes represents that ARAS is functional. Under this condition, alteration of consciousness is likely due to a dysfunction of both cerebral hemispheres.[3]

On the other hand, impingement on the area of the ARAS can abolish the brainstem reflexes and altered level of consciousness even though the cerebral hemispheres are functional. Diffuse cerebral dysfunction usually has a medical basis, such as infections, toxins, or metabolic causes; compression of the ARAS usually is the result of structural disorders of CNS. In children about 90% of nontraumatic coma is due to medical causes.

Diagnostic possibities of altered level of consciousness:

Medical causes

- Anoxia
- DKA
- Electrolyte imbalance
- Encephalopathy
- Hypoglycaemia
- Hypothermia
- Systemic infection
- Inborn errors of metabolism
- Meningoencephalitis
- Psychogenic
- Postictal state
- Toxins
- Uraemia(haemolytic- uremic syndrome)

Surgical causes

- Cerebral vascular accident
- Cerebral venous thrombosis
- Hydrocephalus
- Intracerebral tumour
- Subdural empyema
- Trauma (intracranial haemorrhage, diffuse cerebral swelling, shaken baby syndrome)

Focal neurological signs suggest a structural lesion and lack of focality suggests a medical cause, there are many exceptions. For example, structural disorders that may present without focality include acute hydrocephalus, bilateral subdural hematomas, and acute bilateral cerebrovascular disease. Medical encephalopathies that often present with apparent focal neurological signs include hypoglycaemia, hyperglycaemia, hypocalcaemia, hepatic encephalopathy, uraemia, and the post ictal state that includes Todd paralysis.

The differentiation of medical and structural causes of altered level of consciousness is best assessed by imaging modalities such as computed tomography (CT) scan or magnetic resonance imaging (MRI). Although imaging studies can pinpoint specific structural defects, the presence of certain other findings such as cerebral swelling, and focal neurological abnormalities, it also is important to have a clear understanding of the underlying pathophysiology. Three major responses such as extra ocular movements, pupillary reflexes, and motor responses to pain are helpful for evaluation of both the level and progression of a child's state of consciousness. The pupillary reflex is a balance between sympathetic (pupillary dilators) and parasympathetic (pupillary constrictors) innervations. Because the

pathways that control this reflex is adjacent to the brainstem area that controls consciousness. Any lesions that impinge or affect the brainstem will alter the pupillary size or the ability of the pupil to react to light. For example, a mid brain lesion interrupts the sympathetic and parasympathetic fibres equally, resulting in pupils that are in mid position and fixed; pontine lesion primarily affects the descending sympathetic fibres, causing pinpoint pupils. Expanding lesion in the temporal area of the brain may cause uncul herniation and compress 3rd cranial nerve, leading to a unilateral fixed and dilated pupil on the side of the lesion.

On the other hand, the pupillary reflex is relatively resistant to metabolic insult; also the pupil may be small, they maintain the ability to react to light. Therefore, a child who has unequal, sluggishly reactive , or un reactive pupils should be presume to have brainstem dysfunction in the area of the ARAS and likely a structural cause for the abnormal level of the consciousness, as opposed to a medical cause which would spare the pupillary reflex. For that reason, the presence or absence of the pupillary reflex is one of the most important findings for differentiating structural and medical causes of altered consciousness.

Dysfunction of certain extra ocular movements also may accompany structural causes of altered consciousness. In particular, the oculocephalic reflexes are helpful in assessing low brainstem function. For example, when the head turned to one side in a child who has a functioning brainstem, the eyes move in conjugate fashion, regardless of the level of consciousness. Thus, the eyes move in conjugate fashion (one eye adducts and the other abducts).if there is a brainstem lesion at the level of the medial longitudinal fasciculus, the eyes move disconjugately when the head is turned. If there is a low brainstem lesion, the eyes do not move at all relative to the head.

Finally, motor response to painful stimulus can help localize the level of brainstem dysfunction. Lesion at or above the diencephalic level are associated with decorticate posturing, so the legs stiffen and the arms are rigidly flexed at the elbow and wrist. As the lesion moves rostrally to the level of the midbrain or upper Pons, the arms and legs extend and pronate in response to pain, in what is called decerebrate posturing. If the lesion extents to the medulla, the child's muscle are flaccid, and there is no response to painful stimuli.

Altered level of consciousness suggests that either both of the cerebral hemispheres or the reticular activating system have been

injured.[3] Since this system is thought to modulate arousal and sleep, any interference with it, such as injury, metabolic disturbances or systemic illness could change the level of consciousness.[4]

Alteration of consciousness is a medical emergency that represents the final pathway of various patho physiological processes in disease states (infections, toxic-metabolic, seizures, vascular, neo plastic & trauma) ultimately leading to derangement in cerebral function manifesting as decreased arousal and awareness.[5]

A decreased level of consciousness is correlated with increased morbidity and mortality. Thus it is a valuable measure of a patient's neurological status and outcome.[6]

Altered level of consciousness is a life threatening state of underlying disease process and its management hinges on the understanding of its aetiology and managing complications that may arise. Perhaps the most important thing is being able to identify in a timely fashion those patients with a reversible cause who may benefit from aggressive treatment and have the potential for a favourable outcome.

Following admission in Paediatric Intensive Care Unit, an accurate prognostication regarding survival and functional outcome is needed. This can present a major challenge because of broad range of possible outcomes from death to independent functional recovery.

Although advances in brain imaging, biochemical markers, and electro physiologic studies have aided in accurate prognostication, the clinical neurologic examination remains the foundation of the assessment. Serial examinations are the simplest, least expensive, and often most reliable tool to assess the clinical course.

Numerous scoring scales have been proposed and validated for the evaluation of the level of consciousness for rapid outpatient assessment and triage, severity of the disease, and prognosis for morbidity and mortality.

The ideal scoring system for evaluating altered level of consciousness in children should be easy to administer and score should be applicable to the greatest number of patients and be able to accurately assess level of consciousness, identify rapidly deteriorating patients, and predict morbidity and mortality.

Among the scales developed for assessing the patients with altered level of consciousness are the Glasgow Coma Scale (GCS), the Reaction level Scale (RLS85), the Innsbruck coma scale, AVPU scale and newer one is, the Full Outline of UnResponsiveness (FOUR) score.

Glasgow coma scale:

Glasgow coma scale is the most widely used, most studied and universally accepted coma scale to date.

It was described by Teasdale and Jennett in 1974 and latter revised in 1976 with the addition of a sixth point in the motor response subscale for "withdrawal from painful stimulus"[7,8]

The GCS was initially intended to assess level of consciousness after traumatic brain injury (TBI) in a Neurosurgical Intensive Care Unit in order to facilitate communication among staff regarding patient status.[7] Since then it has become the gold standard against which newer scales are compared and used widely by Emergency department (ED) staff, Medical and Surgical ICU's as well as by pre-hospital providers.

Moving beyond the developers' original indication, the GCS has been validated as a useful tool for prediction of outcome after intracranial haemorrhage,[9] subarachnoid haemorrhage (SAH),[10] poisonings including ethanol,[11-13] neurodegenerative diseases,[14] drowning,[15-16] cardiac arrest,[17-20] recently tuberculous meningitis[21] and prediction of death in palliative care.[22]

The GCS is typically praised for its ease of use, and universal approval. The ease and appeal of the GCS has lead it to be incorporated into many trauma scoring systems, namely the Revised Trauma Score (RTS),[23] the APACHE II,[24] the Simplified Acute Physiology Score (SAPS), and SAPS II,[25] the Circulation, Respiration, Abdomen, Motor, Speech scale (CRAMS),[26] the Traumatic Injury Scoring System (TRISS)[27] and A Severity Characterization of Trauma (ASCOT) scale.[28]

Its simplicity and rapidity of administration have made it popular among emergency medical system (EMS) providers for triage and to guide therapies, and has become a component of many algorithms for out-of-hospital triage to trauma centres.

Although the GCS has not been validated as a prognostic scoring system for infants and young children as it has been in adults, it is commonly used in the assessment of paediatric patients with an

altered level of consciousness.[29] The modified paediatric GCS knows as James' GCS (JGCS) (James and Trauner 1985) are often used by children's examiners to aid monitoring and evaluation of infants and children.

The GCS is the most widely using method of evaluating a child's neurologic function and has 3 components. Individual scores for eye opening, verbal response and motor response are added together, with a maximum of 15 points and minimum of 3 points. Patients with a GCS score less than or equal of 8 require aggressive management, including stabilisation of the airway and breathing with endotracheal intubation and mechanical ventilation, respectively.

Glasgow coma scale: [7,8 & 29]

Eye opening (total possible points 4)

spontaneous	4
To voice	3
To pain	2
None	1

Verbal response (total possible points 5)

Older children		**Infants and young children**	
Oriented	5	Appropriate words; smiles, fixes and follows	5
Confused	4	Consolable crying	4
Inappropriate	3	Persistently irritable	3
Incomprehensible	2	Restless, agitated	2
None	1	None	1

Motor response (total possible points 6)

Obeys	6
Localizes pain	5
Withdraws	4
Flexion	3
Extension	2
None	1

Limitation:

The Glasgow coma scale is the most widely used tool for the evaluation of the level of consciousness. Despite its widespread use it has several well documented limitations.

Based on initial validation studies, the GCS is assumed to be accurate and reproducible; however, many newer studies have found only moderate degrees of inter-rater agreement at best.[30,31,32]

Commonly encountered limitations

- Differential scoring unfairly weights motor subscale.
- Unable to accurately assess intubated/aphasic/aphonic patients, or patients with swollen or injured eyes.
- Not all sub scores are equally validated.
- No direct brainstem evaluation.
- Unable to accurately identify locked - in syndrome.
- Known to be unreliable in inexperienced scorers
- Varied inter- rater reliability.
- The limitation of using this motor-only scale in pharmacological paralytic states.
- Lastly, the GCS has major limitations for its utility in children particularly those less than 3 years of age and prior to acquisition of language.

Many attempts were made over the years to modify or simplify GCS.The Reaction Level Scale (RLS 85) has utility and proven advantage, but minimal acceptance outside of Sweden.[33]

The newer coma scale of Full Outline of UnResponsiveness (FOUR) score provides an attractive replacement for all children with alteration in the state of consciousness and is gradually gaining wide acceptance.

Full outline of unresponsiveness (FOUR) score:

Widjicks et al.,[34] had first proposed and validated this scoring system for measuring impaired consciousness, at 2005 by mayo clinic in adults that overcame some of the shortcomings of the GCS.

The GCS inadequately assesses the cough reflex regardless of level consciousness.

Many coma scales that include indicators of brainstem function have been proposed to supplant the GCS including the Bouzarth Coma Scale for TBI which incorporates brainstem reflexes,[35] the Maryland Coma Scale which includes pupils, caloric reflexes, and grimace,[36] the Comprehensive Level of Consciousness Scale which includes papillary reflexes, eye position, opening, and movement,[37] the Clinical Neurologic Assessment Tool which included Chewing and yawning[38],

and the Glasgow-Liege scale which combined the GCS with five brainstem reflexes: pupillary, fronto-orbicular, occulocardiac, horizontal, and vertical occulocephalic reflexes.[39] These scales generally have been more complex than the GCS and none have gained widespread use.

Recognizing the shortcoming of the GCS, Widjicks et al.[34] published a new scoring system in 2005, the FOUR score, for measuring impaired consciousness that overcame some of the shortcomings of the GCS; critiquing that it lacks the ability to identify subtle changes in alteration of consciousness.

The FOUR score assesses four variables: eye response, motor response, brainstem reflexes, and respiration pattern. A score of 0 represents non- function in each category, while a score of 4 indicates normal functioning. There are 256 possible scoring combinations grouped into 17 possible scores from 0 to 16.

The FOUR score coma scale is superior to Glasgow coma scale in that it can account for the intubated patient without substitute scores and identify a locked-in state, and detect the presence of a vegetative state.

FULL OUTLINE OF UNRESPONSIVENESS SCORE [34,40-41]

EYE RESPONSE

Eyelids open or opened, tracking or blinking to command	4
Eyelids open but not to tracking	3
Eyelids closed but opens to loud voice	2
Eyelids closed but open to pain	1
Eyelids remain closed with pain stimuli	0

MOTOR RESPONSE

Thumbs up, fist or peace sign	4
Localizing to pain	3
Flexion response to pain	2
Extension response	1
No response to pain or generalized Myoclonus status	0

BRAINSTEM REFLEXES

Pupil and corneal reflexes present	4
One pupil wide and fixed	3
Pupil or corneal reflexes absent	2
Pupil and corneal reflexes absent	1
Absent pupil, corneal, or cough reflex	0

RESPIRATION

Regular breathing pattern	4
Cheyne – stokes breathing pattern	3
Irregular breathing	2
Triggers ventilator or breathes above ventilator rate	1
Apnoea or breathes at ventilator rate	0

Proposed to replacement for GCS. Several studies were validated in adults, but limited studies only available in paediatric population

Advantages of the FOUR score over GCS:

The FOUR adds to the eye opening of the GCS by testing eye tracking, thus incorporating midbrain and pontine functions.

Adding to the motor score of the GCS is an extension of Wijdick's[34] earlier work incorporating hand gestures into the evaluation. This alternative to the verbal score allows for testing of afferent language processing and remains testable regardless of endotracheal intubation, aphasia, aphonia, or trauma to the vocal apparatus. The bulk of the motor score is similar to the GCS except that no difference is delineated between flexor posturing and normal flexion to pain. Additionally, no motor response and myoclonic status

epilepticus are scored equally, reflecting the associated poor outcome after anoxic brain injury.[40]

Specific testing of brainstem reflexes via pupillary, corneal, and cough reflexes further allows the practitioner to localize lesions and track progression of cerebral injury specifically by addressing unilateral fixed mydriasis, a sign alerting to uncal herniation.

The final category of the FOUR score evaluates patterns of respiration.This assesses respirations as spontaneous regular or irregular, Cheyne-Stokes, intubated but independently breathing above the ventilator, or absent.

REVIEW OF LITERATURE:

Teasdale and Jennet (1974) was first described the Glasgow coma scale from expanded on the work on ommaya and others, it was initially called as the coma index. The GCS was initially developed to asses the severity and depth of coma and to improve communication between healthcare providers with different states of experience and expertise.

Rowley and Fielding (1991) found that, by using the GCS, inexperienced health care providers demonstrated significant variability where as experienced raters were able to assess a patient with high levels of accuracy and reliability, particularly in the border line level of consciousness.

Gill, Reiley, and Green (2004) found that, GCS has only moderate degrees of inter-rater reliability in the ED setting. This is consistent with the observations of a national survey which showed variation among trauma centers (Buechler et al.1998).

Riechers et al. (2005) reported many physicians were not able to accurately identify the scales subcategories and the specific points of each. Clinician with advanced qualification and underwent training in

emergency department performed significantly better than those had less experience. *Healey et al., (2003).* Well known documented limitation to the GCS was the verbal component and its usefulness in assessing critically ill, especially in intubated, neuroscience patients. The presence of an ET tube eliminates the ability to assess verbal components of GCS. The need for mechanical ventilation, however, may denotes brainstem involvement and one of the most essential factor in the evaluation of coma severity. These patients are high risk for in-hospital mortality and poor neurological outcome. Methods were using to overcome this limitation have included: assigning all intubated patients with the lowest verbal score (1 point), pseudoscoring that predicts the patient's ability to verbalize, or simply designating a nonnumeric score of" T" to all intubated patients *(Rutledge et al., 1996).*

These methods of evaluating the Glasgow coma scale in the presence of ET tube have not been validated and not widely accepted also. The verbal response categories of Glasgow coma scale also have a challenge in the evaluation of infants and preverbal children. To account for the developmental variations in the verbal, as well as the parents and cognitive ability of infants and children, a modified

paediatric GCS was developed in view of developmental variation in the language and cognitive ability of infants and children. There have been many attempts through years to develop and validate additional paediatric scales including the CHOP Infant Coma Scale *(Durham et al.,2000),* the Adelaide Paediatric Coma Scale *(Reilly,Sprod, Simpson & Thomas,2004),* and the Starship Infant Neurological Assessment Tool *(Birse,2006).* Despite these attempts, there is currently no agreed- upon" gold standard" for paediatrics *(Tatman et al.,1997).*

Additional key clinical indicators that are necessary for a neurological assessment which are usually not assessed when using the GCS include asymmetry of pupils, abnormalities in ocular movement, and changes in respiratory patterns. Subtle changes of those brainstem reflexes and cranial nerve functions may indicate brainstem injury and neurological impairment *(Youman,1996).*

Teasdale and Jennett (1974) was recognized that testing of brainstem function can be useful in the diagnosis of altered level of consciousness and yet chose not to incorporate brainstem assessment into GCS.

Wijdicks et al., (2005). To address the many limitation of GCS, researchers at the mayo clinic designed the four score coma scale as a proposed alternative.

Wijdicks, et al. Department of Neurology, Mayo Clinic.2005, they evaluated the FOUR score prospectively in 100 patients during May 1-2007 to April 30, 2008. Observations were similar to that of Glasgow coma scales with excellent inter observer agreement with the FOUR score. Weighted k value of FOUR score for eye response,0.96; motor response, 0.97; brainstem reflexes,0.98; respiration pattern, 1.00, was similar with GCS weighted k value (eye response, 0.96; motor response, 0.97; verbal response, 0.98). Receiver operating curve was 0.7 and 0.76 for the FOUR score and the GCS respectively. Neurological outcomes were assed with modified ranking scale. Mortality with lowest GCS score of 3 was 71% and for lowest FOUR score of 0 was 89%, it was higher than GCS mortality prediction. This study concluded as excellent inter rater agreement for FOUR score among medical intensivists. Even when the patients have undergone intubation all components of the FOUR score can be rated easily. So the FOUR score is a good predictor of patients admitted in ICU setting and has several advantages over the GCS.

Jennifer Cohen et al.,conducted prospective study among the children 2 to 18 years of age at CHOC Children's hospital, Orange country CA with aim of to compare the inter- rater agreement and predictive validity between the FOUR score and the GCS in children.

Sample size: 60 children admitted in PICU.

Conclusion:

- Weighted kappa for FOUR score total 0.951 –very good.
- Weighted kappa for GCS score total 0.738- good.
- FOUR score better of outcome (71% of patients' correctly classified Vs 63% with GCS)
- Nurses found the FOUR score clinically relevant and easy to use.

J. E. Fugate et al. study done prospectively in 136 post cardiac arrest patients admitted in from June 2006 to October 2009 at department of neurology, mayo clinic. Out 136 patients, 82% of patients examined on days 1- 2 after cardiac arrest and 64% were examined on days 3-5. Of those 47 patients got discharged and 89 died during hospitalization. None of the patients with sum FOUR score less than 4 on days 3- 5 examination survived with false positivity rate of 0% and C.I. 0.000-0.0345, but one patient with lowest GCS score of 3 survived to

discharge with FPR of 2.2%, Confidence Interval < 0.0001-0.1758. Patients with >8 sum FOUR score, 41 of 45(91%) were survived ($p<0.0001$), whereas in GCS 39 of 45 discharged with sum GCS score of >6 ($p<0.0001$).conclusion: outcome prediction of the FOUR score is superior to the GCS.

Chris A Wolf, RN, Eelco F. M. Wijdicks, MD, and colleagues prospectively studied about prediction of the FOUR score in 80 patients admitted at mayo clinic intensive care unit with acute neurological disease and compared its performance with cold standard coma scale of Glasgow coma scale (GCS) by using ICU nurses. They were randomly selected from experienced and inexperienced neuroscience and non neuroscience nurses. All nurses were trained with video examples and instruction cards. Each patient was studied by 2 nurses, they were assigned randomly.

Results:

Inter observer reliability was good to excellent in both coma scales. Among the raters experienced neuroscience had less disagreement, but there was no statistically significant difference among them.

Conclusion:

Compared to the GCS, the FOUR score is neurologically more informative and can be used by any health providers even those with minimal experience.

Two recent studies have validated the use of the FOUR score outside of the Mayo Clinic.

Weiss and colleagues at the hospital de la Pitie-Salpetriere, Paris, France translated the FOUR score into French and assessed its utility and validity in a neurologic critical care unit. A total of 176 FOUR scores were calculated by two neurologists, four experienced nurses and five inexperienced nurses. This was consistent with prior validation studies (weighted j was 0.86 for the FOUR score and 0.85 for the GCS).[42] The French team highlighted that the FOUR score was useful, easy to learn and easy to perform.

Akavipat et al. further validated and endorsed the use of the FOUR score specifically for neurosurgical patients[43]. 100 patients were evaluated to assess inter - rater reliability of each the Full outline of unresponsiveness score and the Glasgow coma scale, and also to compare scoring between the two. Patients were assessed by expert clinicians, novice clinicians, experienced nurses, and inexperienced

nurses. Weighted j scores among the types of rater varied from 0.93 to 0.99 for the FOUR score and 0.9–0.97 for the GCS. The poorest agreement was in the brainstem subscale. The author points out potential pitfalls of brainstem scoring that may be variable among examiners including the loudness voice, intensity of applied noxious stimuli, potential pupil size estimation, and fluctuations between ratings.

STUDY JUSTIFICATION

- Prognostication for survivors of children admitted with altered level of consciousness is a frequent challenge to intensivists.
- The Glasgow coma scale is the most widely using tool for predicting outcome of children in our Paediatric Intensive Care Unit. It has number of shortcomings, including limited utility in intubated children and inability to assess brainstem reflexes.
- The Full Outline of Unresponsiveness coma score overcome these shortcomings, and making it fully applicable in intubated /aphonic / aphasic children.
- In contrast to the GCS, four score is simple, user friendly & provides far better information, particularly in intubated children because verbal response is not a component of the four score
- This scoring system ignores disorientation or confusion used in the verbal scale, but provides a good assessment of eye movements, brainstem reflexes, and respiratory drive.

AIM OF THE STUDY

To determine whether the FOUR (Full outline of unresponsiveness) score is an accurate predictor of outcome in children with altered level of consciousness.

MATERIALS AND METHODS

METHODOLOGY :

STUDY DESIGN : Prospective study

STUDY PLACE: Department of Paediatric Intensive Care Unit (PICU), Institute of Child Health and Hospital for children (ICH & HC), Egmore, Chennai.

STUDY PERIOD: January 2011 to October 2011

STUDY POPULATION: Children admitted with altered level of consciousness in the Paediatric Intensive Care Unit, Institute of Child Health and Hospital for children, Egmore, Chennai.

CASE DEFINITION:

Altered level of consciousness defined as conscious level is below or equal to "V "in abbreviated coma scale.(AVPU Scale)[44]

V - VOICE – the child responds only when the parents or examiner/physician call the child's name or speak loudly.

P – PAINFUL – the child responds only to a painful stimulus, such as pinching the nail bed

U- UNRESPONSIVE- child does not respond to any stimulus

INCLUSION CRITERIA

All children admitted in Pediatric intensive care unit who met the case definition during the study period were enrolled in this study.

EXCLUSION CRITERIA

- Children who died within 6 hours of admission,
- Children with pre existing neurological illness, cerebral palsy and developmental delay and children on continuous neuromuscular blockade drugs.

SAMPLE SIZE

A 173 (all children admitted with altered level of consciousness, who met the eligibility criteria during the study period).

SAMPLING TECHNIQUE: Nil

MANEUVER

Children, who have admitted in at the PICU during the period between January 2011 to august 2011 with altered level of consciousness, were recruited in this study based on inclusion and exclusion criteria after obtaining written informed consent from the parents or caregivers.

Basic information regarding childs' age, gender, address with phone number for follow up, place of referral (emergency department, or general medical ward), intubation status, if intubated , reason for intubation and administration of any premedication during intubation was obtained and entered in patient data entry form.

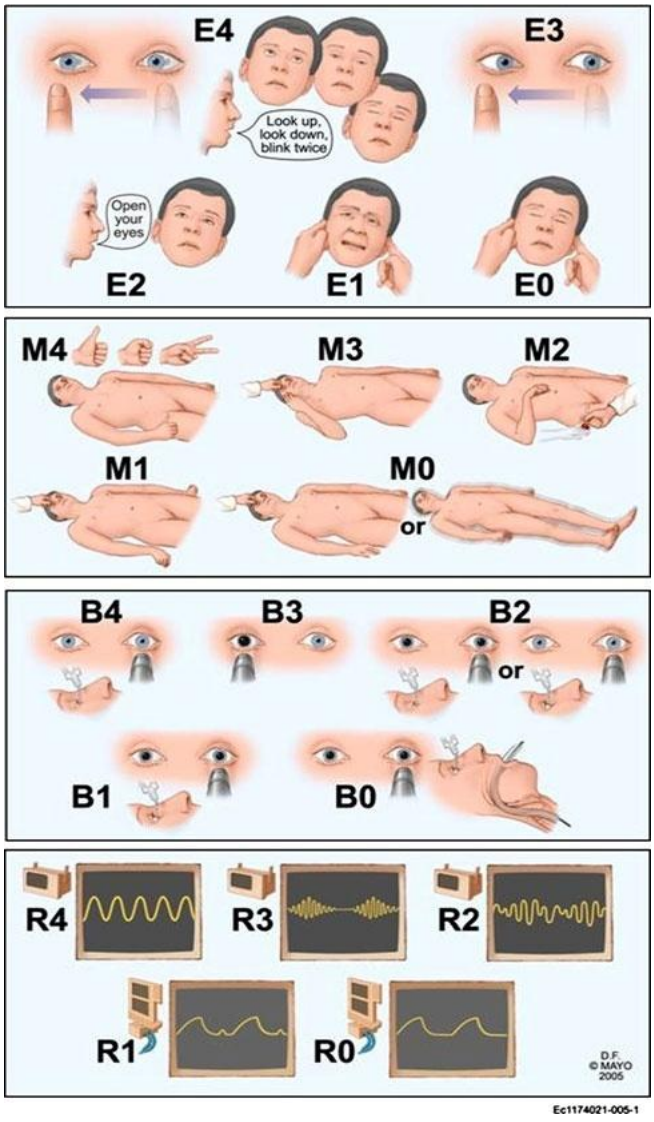
Detailed clinical and neurological examination was done in all study children.

Full outline of unresponsiveness score was performed on day1- 2 after admissions in the intensive care unit and then daily till discharge or death. Initial score was taken for statistical analysis.

Patients were examined in the absence of paralytic and sedative medications.

In-hospital mortality, clinical diagnosis of brain death and survival at discharge were recorded for all children. Primary outcome was in-hospital mortality.

FOUR SCORE EXAMINATION METHODS[34]



Eye response: E4 to E1; Motor response: M4 to M1; Brainstem reflexes: B4 to B1; Respiratory pattern: R4 to R1. Individual components and their points details given in page no 21 and 22 under the heading of FOUR score.

Neurological outcome was assessed in the child > 2 years after three months, in survived at discharge children with the Modified Rankin Scale[45]

Modified Ranking Scale[45]

Neurological outcome in after discharge	**Score**
No symptoms	0
No evident disability despite symptoms	1
Slight disability, with an inability to carry out all previous activities	2
Moderate disability, with need some help but ability to walk without assistance	3
Moderately severe disability, with the inability to walk without assistance or to attend to bodily needs without assistance	4
Severe disability, with the patient being bedridden and incontinent and requiring constant nursing care	5
death	6

Statistical analysis:

We have used the following statistical methods to arrive our conclusion.

Descriptive statistics (frequency tables, mean & standard deviation), graphical analysis, correlation analysis, chi-square independent test, analysis of variance (ANOVA), and logistic regression.

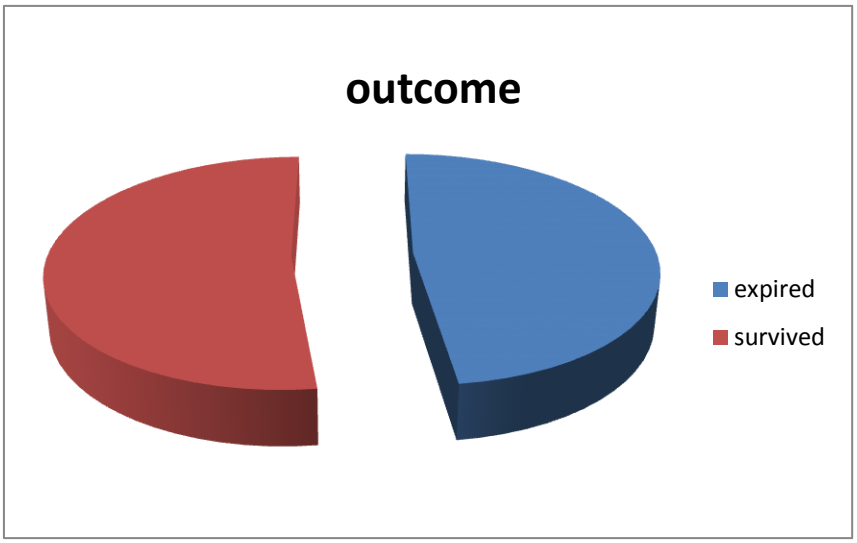
RESULTS

Baseline characteristics of the study population:

Table: 1.

	Total	Outcome	
		Dead	Alive
Total Children	173	83	90
Mean 4 Score		4.84	10.52

Figure: 1.



A total of 173 children were enrolled in our study. In that, 83(47.97%) expired in- hospital and 90(52.02%) children were

discharged. The mean FOUR score for in- hospital mortality and survival at discharge were 4.84, and 10.52 respectively.

Demographic descriptive analysis:

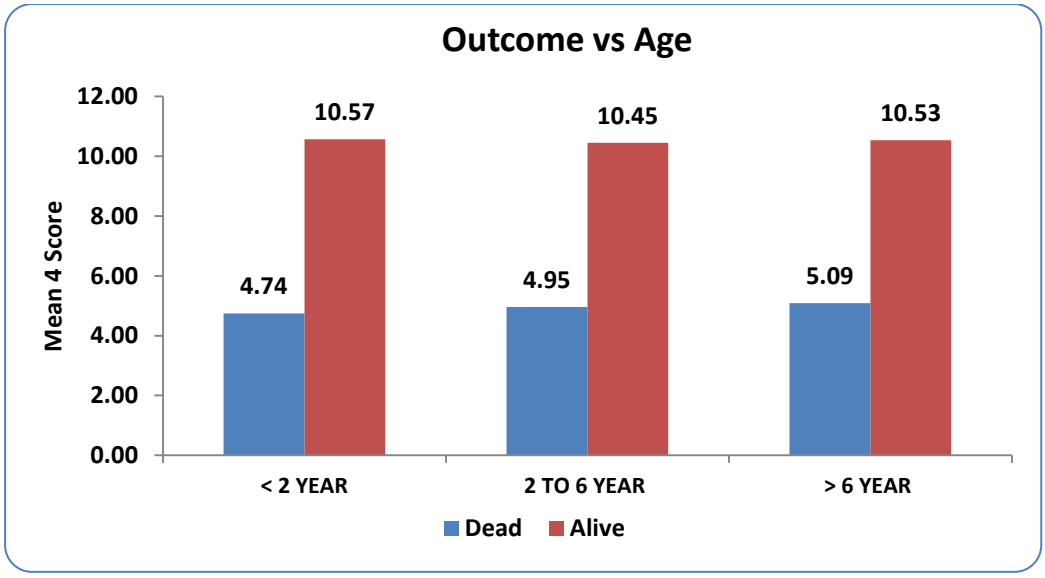
Age distribution:

Table: 2.

Age	Total children n(%)	Age		
		Dead n(%)	Alive n(%)	Mean 4 Score
< 2 Year	96(55%)	50(52%)	46(48%)	7.53
2 To 6 Year	51(29%)	22(43%)	29(57%)	8.08
> 6 Year	26(15%)	11(42%)	15(58%)	8.23

P Value - 0.696.

Figure: 2.



In our study, mean age was 3.4 years ranging from 6 months to 12 years with standard deviation +/- 3.2 years.

In those, ninety six (55%) children were less than 2 years. Among 96 children, in hospital mortality was 52 %(50) with mean score of 4.74 and 48% (46) of children with mean score of 10.57 were discharged. Fifty one (29%) children were between the age group of 2 to 6 years, in those mean FOUR score for in-hospital death (43%) and survival at discharge (57%) was 4.95 and 10.45 respectively. Remaining 26(15%) children were above 6 years, among those 42 %(11) of children with mean four score of 5.09 were expired and 58 %(15) had mean four score of 10.53 got discharged.

In this study there was no statistically significant difference in the mean FOUR score among the different age groups. In all the age group there was statistically significant difference in the mean FOUR score between in-hospital mortality and survival at discharge.

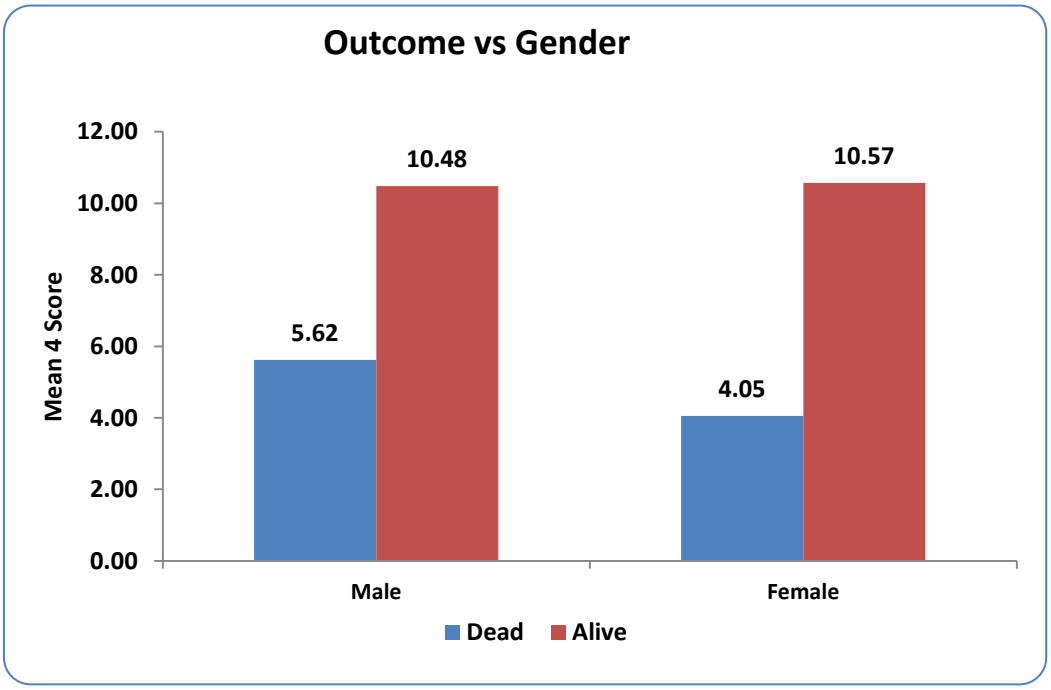
Sex distribution:

Table: 3.

Sex	Total n(%)	Outcome		Mean 4 Score
		Dead n(%)	Alive n(%)	
Male	88(51%)	42(48%)	46(52%)	8.16
Female	85(49%)	41(48%)	44(52%)	7.42

p value - 0.223

Figure: 3



Out of 173 children, 88(51%) were male and 85(49%) children were female. Among these groups 48% of children expired and 52% were discharged. In male children, mean four score for survival and death were 10.48 and 5.62. Similarly in female children were 10.57 and 4.05 respectively.

There was no statistically significant difference in the mean FOUR score between two groups.

Clinical descriptive statistics:

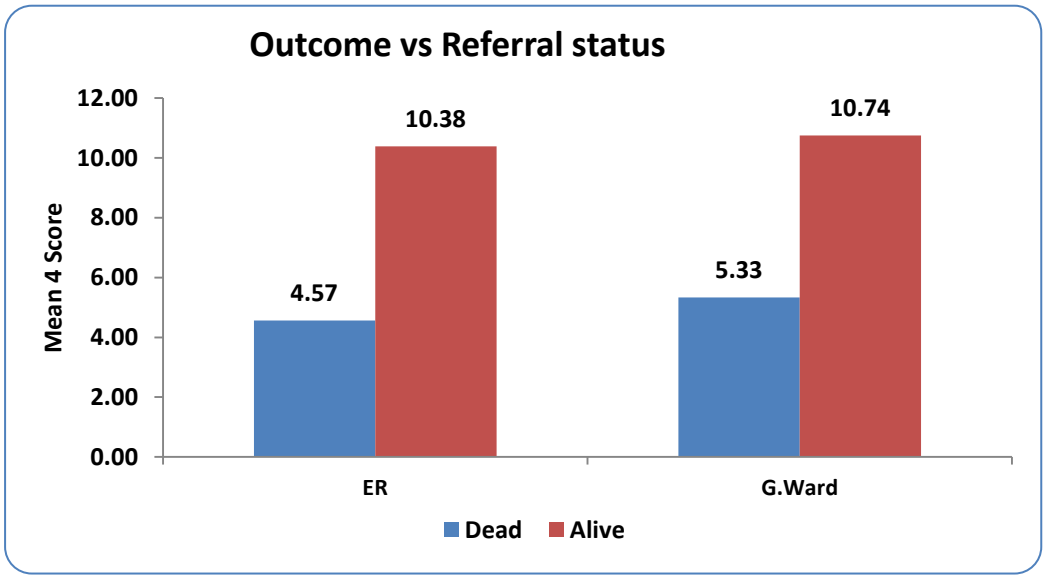
Referral status:

Table: 4.

. Referred from	Total n(%)	Outcome		Mean 4 Score
		Dead n(%)	Alive n(%)	
ER	108(62%)	53(49%)	55(51%)	7.53
General Ward	65(38%)	30(46%)	35(54%)	8.25

p value - 0.249.

Figure: 4.



Among the study population, 108(62%) were admitted directly from emergency department after initial resuscitation. Remaining sixty two (48%) children from general medical ward, in view of worsening in ward and requiring intensive care.

In those children's outcome and their mean four score for in-hospital mortality and survival at discharge is depicted above table 4 and figure 4.In this study there was no statistical significance among the FOUR score with respect to place of referral.

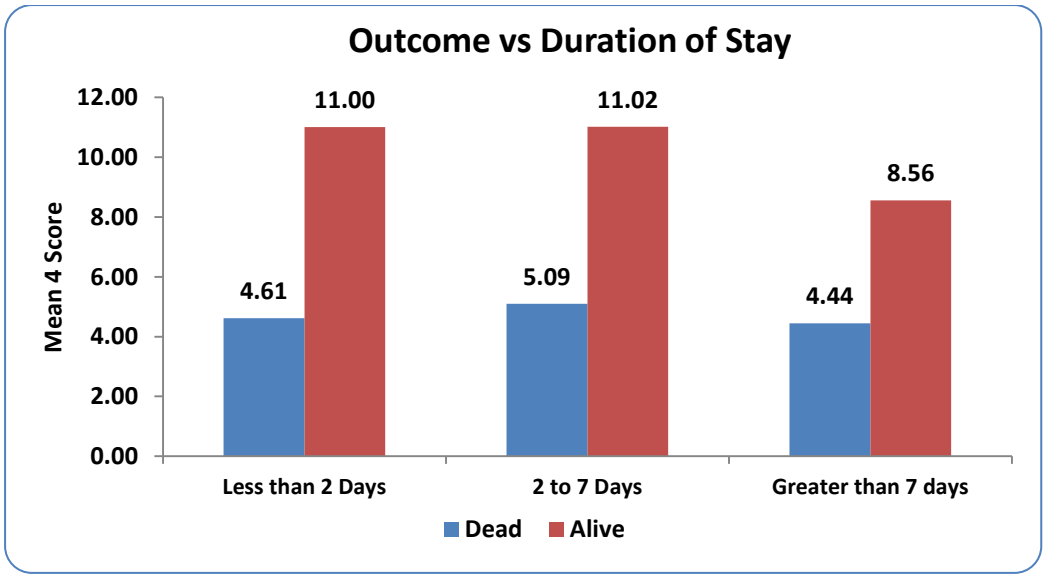
Duration of hospitalisation:

Table: 5.

Stay duration	Total n(%)	Outcome		Mean 4 Score
		Dead n(%)	Alive n(%)	
Less than 2 Days	47(27%)	31(66%)	16(34%)	6.79
2 to 7 Days	99(57%)	43(43%)	56(57%)	8.44
Greater than 7 days	27(16%)	9(33%)	18(67%)	7.19

p value-0.041.

Figure: 5.



In our study, mean duration of hospital stay was 5.4 days ranging from 28 hours to 26 days. Of those total children, forty seven (27%) children stayed less than 48 hours with mean FOUR score of 6.79. Ninety nine (57%) children stayed more than 48 hours to one week with mean FOUR score of 8.44. Remaining 27(16%) children stayed more than a week, in those mean FOUR score was 7.19.

Of those children's outcome based on duration of hospitalisation and their mean four score for death and survival is depicted in above table 5 and figure 5.

The difference in mean FOUR score was statistically significant between the three groups.

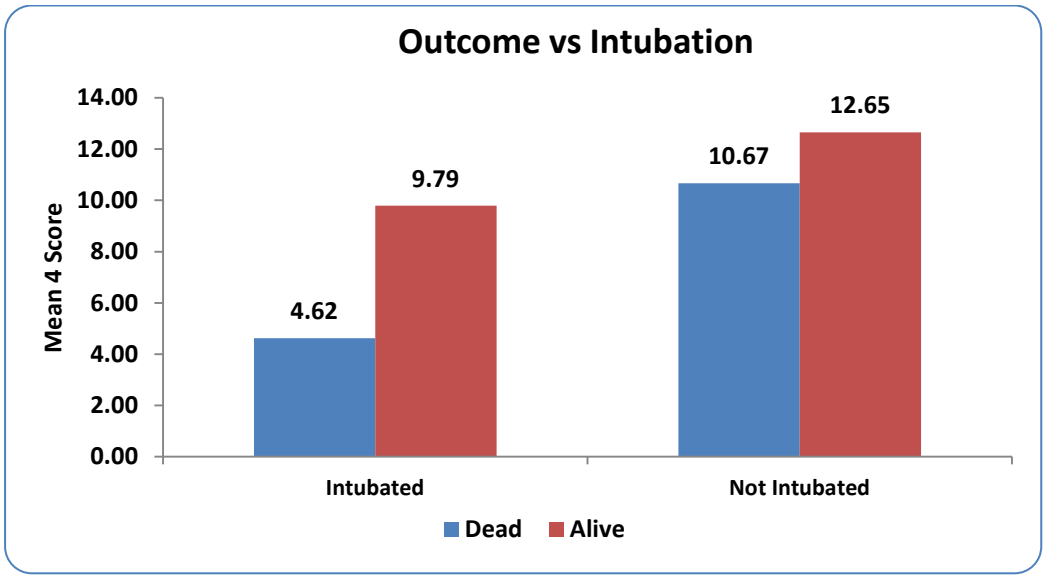
Intubation status:

Table: 6.

Intubation status	Total n(%)	Outcome		Mean 4 Score
		Dead n(%)	Alive n(%)	
Intubated	147(85%)	79(54%)	68(46%)	6.98
Not Intubated	26(15%)	3(12%)	23(88%)	12.42

P value< 0.001

Figure: 6.



In our study, 147(85%) children were on mechanical ventilation support and their mean FOUR score was 6.98. Remaining 26(15%) were not on mechanical ventilation, those children had mean FOUR score of 12.42.

In these group children's outcome and mean four score for in-hospital mortality and survival at discharge is given in above table 6 and figure 6.

As we were all well known, there was a significant statistical difference in the mean FOUR score among the intubated and non intubated groups.

Clinical diagnosis:

Table: 7.

Diagnosis	Total	Outcome		Mean 4 Score
		Dead	Alive	
CNS INFECTION	48(28%)	44%	56%	6.38
BRONCHIOLITIS	22(13%)	18%	82%	10.14
PNEUMONIA	40(23%)	48%	53%	8.35
METOBOLIC	22(13%)	68%	32%	7.18
VHF	14(8%)	79%	21%	5.36
POISONING	11(6%)	27%	73%	11.18
OTHERS	16(9%)	63%	38%	8.13

p value < 0.001.

Figure : 7

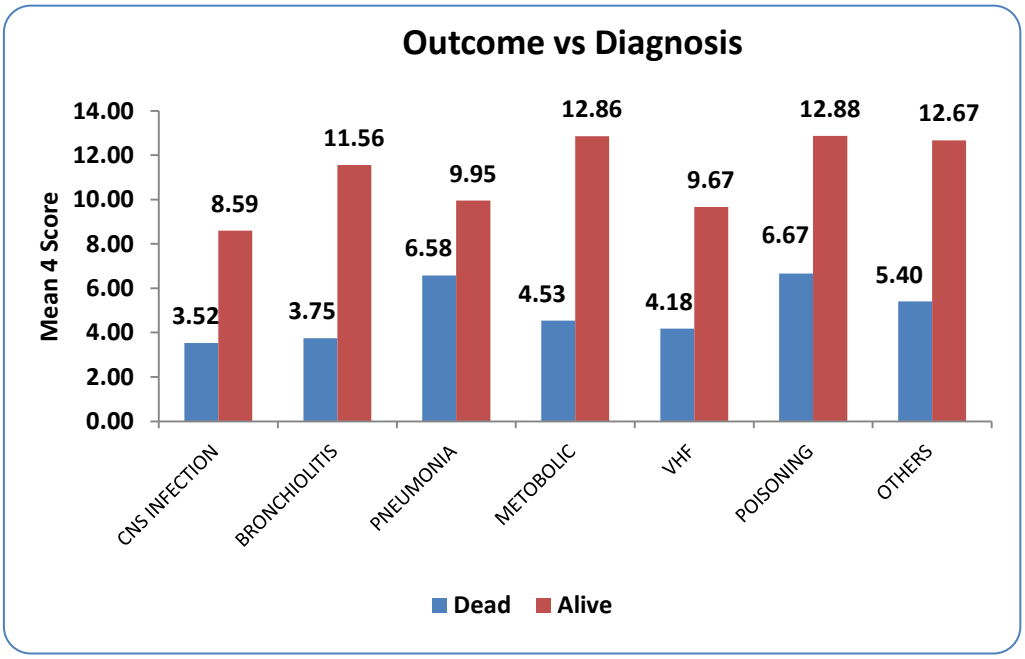
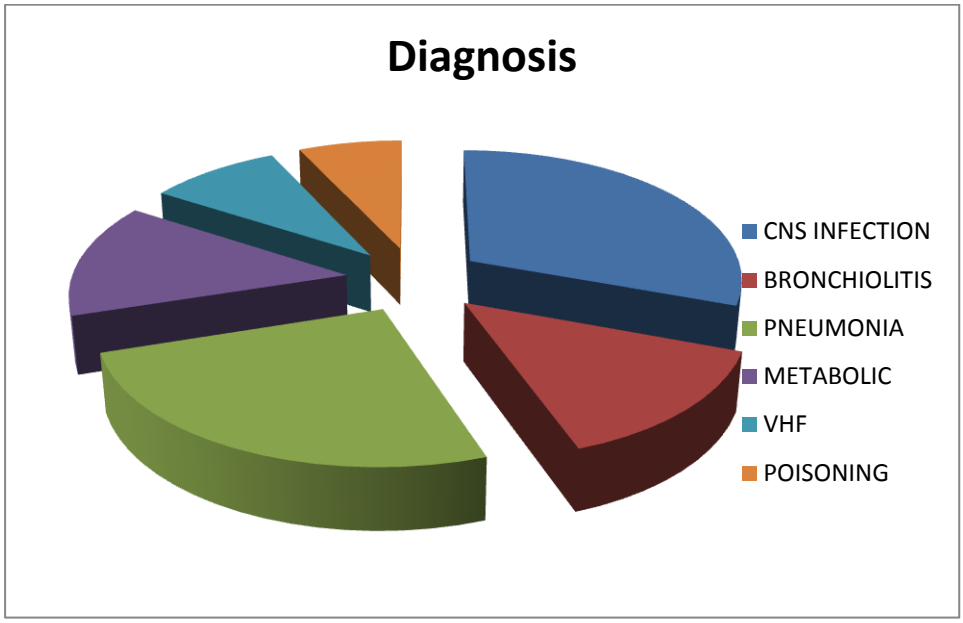


Figure: 8.



Among 173 children examined, 48(28%) children diagnosed as CNS infection (bacterial, viral, & TB meningitis, meningoencephalitis and cerebral malaria) with mean FOUR score of 6.38. In those 48 children, 21 (44%) died in hospital and remaining 27 (56%) got discharged.

Bronchiolitis was diagnosed in twenty two (13%) children with mean FOUR score of 10.14. Among those 22 children, 4(18%) expired and remaining 18 (82%) children were discharged.

Forty (23%) children affected by pneumonia and their mean FOUR score was 8.35; among those 19(48%) and 21(52%) children expired and survived at discharge respectively.

Metabolic causes such as uraemia, diabetic ketoacidosis, hepatic encephalopathy, electrolyte abnormalities and inborn errors of metabolism were responsible for 22(13%) admissions and in these children's mean FOUR score was 7.18. Among these 15 (68%) expired and 7(32%) children got discharged.

Fourteen (8%) cases were diagnosed as hemorrhagic fever including dengue fever and rickettsial infection, with mean FOUR score of 5.36. In these children in- hospital mortality and survival at discharge were 11 (79%) and 3 (21%) respectively.

Eleven (6%) children were admitted due to poisoning (kerosene, snake envenomation and scorpion sting, etc) with mean FOUR score of 11.18. Among these 11 children, 3 (27%) expired in-hospital and 8 (73%) children got discharged.

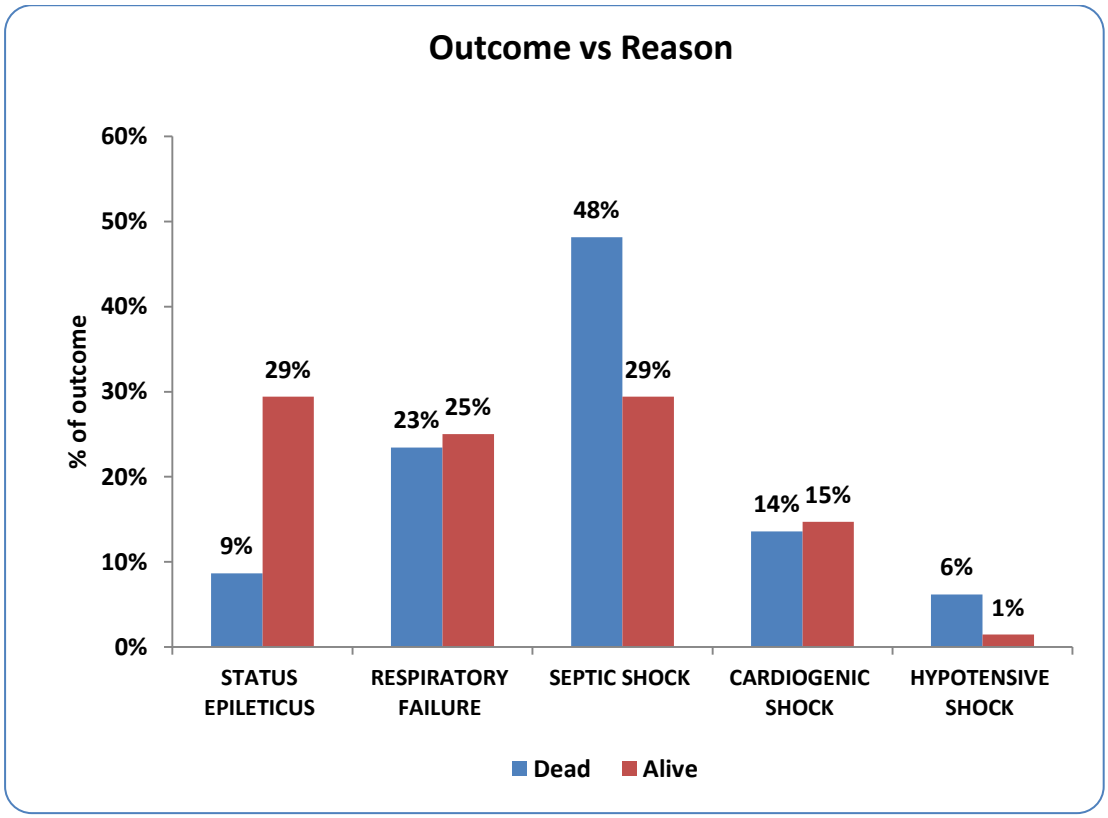
Sixteen (9%) children got admitted with other diagnosis (heart disease, septic arthritis and submersion) with mean FOUR score of 8.13; among these, 10(63%) children expired and 6(38%) children survived.

In these diagnostic groups, mean four score for in-hospital mortality and survival at discharge is given in above figure 7.

In this study there was a significant statistical difference in mean FOUR score and between the mortality groups and survival groups irrespective of aetiology.

Reason for intubation Vs Outcome

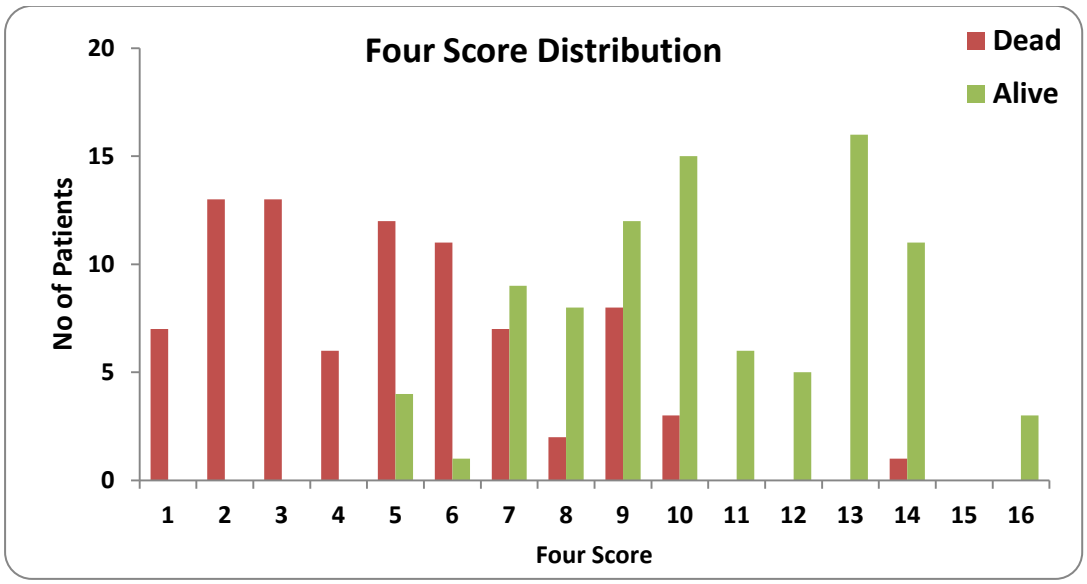
Figure : 9.



In our study, 147 children were intubated due to various reasons (septic shock, cardiogenic shock, hypotensive shock and respiratory failure and status epilepticus); in these mechanical ventilated children in- hospital mortality and survival at discharge is given in above Figure - 9.

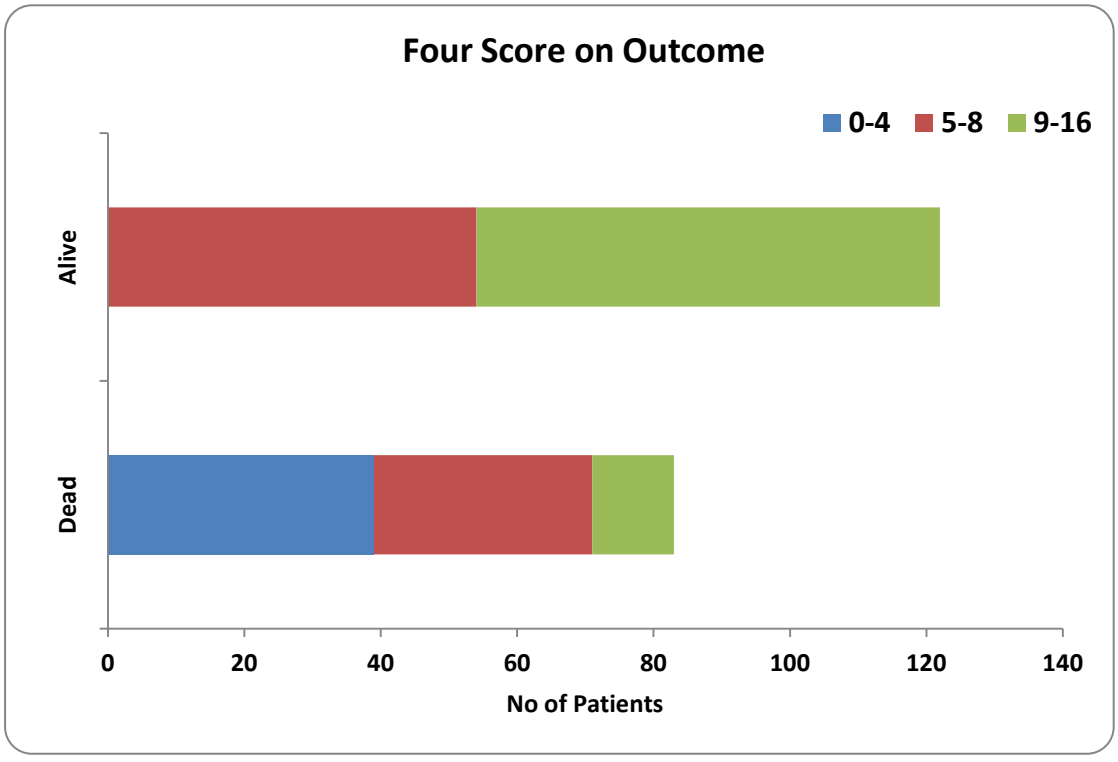
Score wise distribution of study population:

Figure: 10.



In-hospital mortality decreases with increasing the score

Figure: 11.



Ranges of FOUR score and mortality:

Table: 8.

No	Four score	Total cases	mortality	Mortality%	discharged	Discharged %
1	4 or less	39	39	100%	0	0%
2	5 to 8	50	32	64%	18	36%
3	9 to 10	42	11	26%	31	74%
4	>10	42	1	2.4%	41	97.6%

In- hospital mortality is higher with lowest sum FOUR score. Mortality risk is found to be decreasing with increase in the total FOUR score.

Four score outcome analysis:

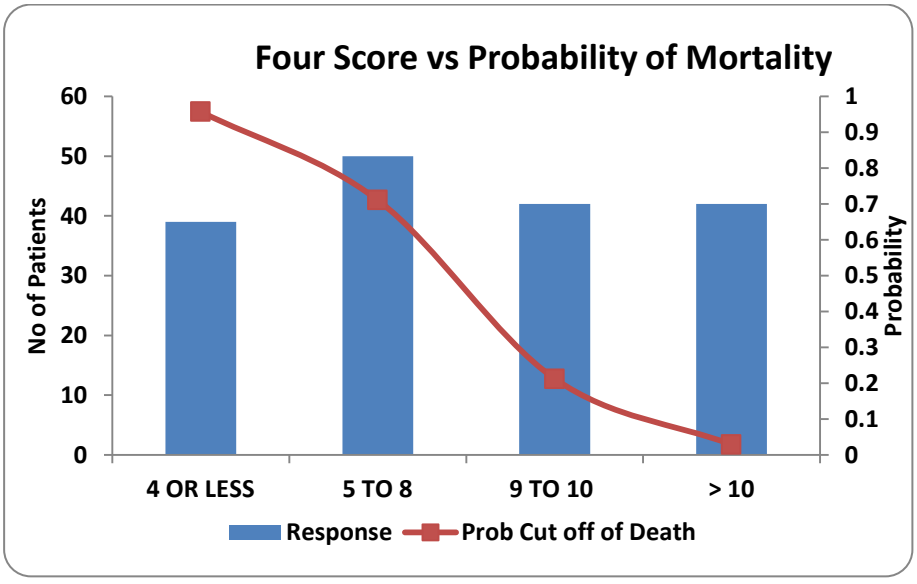
Table: 9.

Four Score Level	Probability Cut-Off	Sensitivity	Specificity	PPV	NPV	FPR	FNR
4 or less	0.957268878	0.470	1.000	1	0.671642	0	0.53012
5 to 8	0.710796377	0.855	0.800	0.64	0.585366	0.2	0.614458
9 to 10	0.212378623	0.988	0.456	0.261905	0.450382	0.344444	0.86747
>10	0.02873318	1.000	0.000	0.02381	0.374046	0.455556	0.987952

Chi square value: 90.4038. p value: <0.0001.

Score is significant with outcome at 95% C.I. with chi square value of 90.4038 (p= <0.001).

Figure: 12.



One hundred and seventy three children examined in our study on days 1- 2 after admission in PICU. Of those, thirty nine (22.%) children had a sum FOUR score 4 or less and none (0%) survived to discharge, yielding a specificity of 100%, sensitivity of 47%, positive predictive value of 100%, and false positivity rate of 0%. Fifty (30%) children had a sum FOUR score of 5- 8, yielding a specificity of 80%, sensitivity of 85%, positive predictive value of 64%, and false positivity rate of 20%. Forty two (24%) children had sum FOUR score of 9-10, yielding a specificity of 46%, sensitivity of 99%, and positive predictive value of 26%, and false negativity rate of 87%. Forty two (24%) children had sum FOUR score of 10 and above with sensitivity of 100% , specificity of 0% , positive predictive value of 2%, and false negativity rate of 99%.

Receiver operating curve;

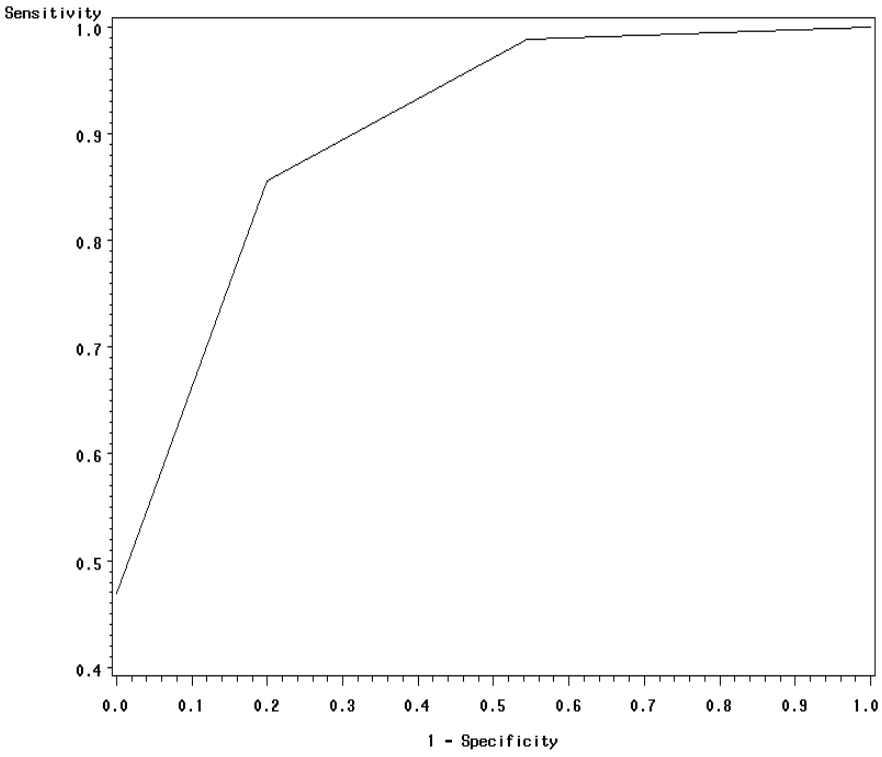
The ROC curve is a graphical representation of the discriminative power of a test. Area under the ROC curve is an effective way to summarize the overall diagnostic accuracy of the test.

If one cut off point is chosen to differentiate from death to survival, at the extremes of the range there are bound to be false positives and false negatives. Thus we require that optimal cut-off

point where both sensitivity and specificity are optimal. The test is said to have good performance if the area under the curve nears 1. A 0.5 result is interpreted as worthless as this could be by pure chance and the four scoring system has not had a good discriminative power.

ROC curve:

In this study, the area under the ROC is 0.903 with optimal sensitivity of 85% and optimal specificity of 80% at best cut-off score of 7.



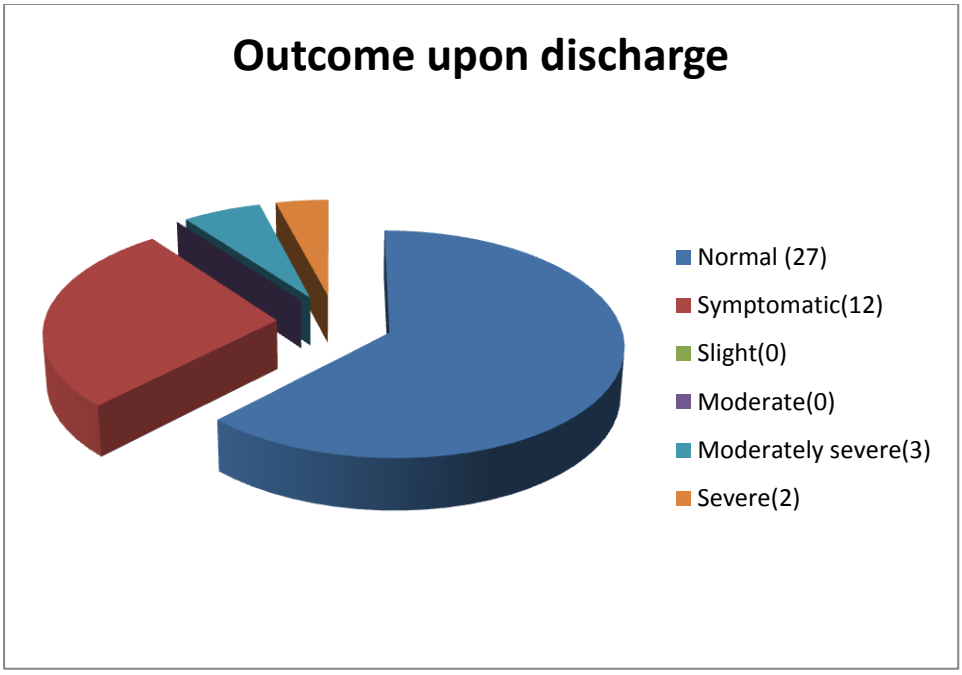
Areas under the ROC curve - 0.903(90%).

Outcome upon discharge: Modified ranking scale

Total children survived at discharge – 90

In those children, Less than two years – 46, and above two years – 44 children. Only above 2 years children survived at discharge, were taken up for neurological outcome assessment after 3 month of discharge, because of difficulty in application of this scale in less than 2 years.

Figure: 13.



Discussion

In this study we prospectively examined in 173 children in the age group of 6 months to 12 years. This is slightly different from Jennifer Cohen et al., study, done in 70 children between the age group of 2 to 18 years.[46]

We observed in our study among the four variables of the FOUR score; respiration has the least correlation with total score compared with other variables (eye response, 0.91; motor response, 0.89; brainstem reflexes, 0.84; and respiration, 0.76). This can be explained by the fact that 85% of children were in mechanical ventilation support in our study and in a child under mechanical ventilation, only two patterns were included in the scoring; either "apnea or triggered ventilation", which could have lead a poor correlation with the total score.

While applying the normal functioning motor scale of FOUR score, we noted some difficulty in less than 2 years, because the developmental differentiation of language and motor milestones in this age group interference with assessment of response. So we used in our

study, spontaneous movement/ obey commands instead of thumbs up, fist or peace sign as in original validation study. [34, 40]

In our study, we observed there was no statistically significant different in the mean FOUR score among the age group, sex and place of referral. We also noted there was significant difference in the mean FOUR score with respect to duration of hospitalisation, mechanical ventilation and diagnosis.

Among total in-hospital mortality, 47% occurred within 48 hrs of admission, because vast majority of the low FOUR score children died in this period. In our study viral hemorrhagic fever and metabolic diseases had low mean FOUR score with poor outcome, and bronchiolitis had high mean FOUR score with better outcome.

We observed in our study, no children survived at discharge with sum FOUR score of 4 or less, yielding a specificity of 100% and FPR 0% ($p<0.00.$). We also found vast majority of children with sum four score more than 8 survive to hospital discharge and most of the children at discharge are fully conscious. In–hospital mortality risk was decreased with increasing score. FOUR score prediction of in-hospital mortality in sum FOUR score of 4 or less is similar to the Jennifer E. Fugate et al., study done in post cardiac arrest patients.[47]

Our study has 0.903(90%) accurate prediction for outcome as per ROC curve and high specificity in lower sum FOUR score that means more than 97% of children will die if sum FOUR score is 4 or less. Similarly more than 99% of children will survive if sum FOUR score is > 10.

In our study, we also observed some of the children with initial four score above 8 subsequently developed sudden worsening resulting in poor outcome. This might be because of secondary complication of mechanical ventilation like pneumothorax and ventilator associated pneumonia (VAP) which cannot be predicted.

Most of the children who survived at discharge were fully conscious. Out come upon discharge is assessed 3 months later. Most of the children had a normal outcome, but some children who got discharged with low mean FOUR of 5.92 developed moderate to severe disability (4 to 5) in modified ranking scale. One child who was a chronic liver disease died on follow up because of severe respiratory infection.

Limitation of this study:

- Score was not compared with GCS which is till now the gold standard coma scale.
- Scoring was not done at uniform time in this study.
- Children Less than 2 years who survived at discharge were not taken for outcome analysis after discharge, because of difficulty in utilization of modified ranking scale in this age group. So, the usefulness of this score in predicting long term outcome could not be studied.

CONCLUSION

- The FOUR score is able to accurately predict outcome in children with altered level of consciousness admitted at paediatric intensive care unit with respect to in-hospital mortality and survival at discharge.
- The score is uniformly applicable to different age groups and to different aetiological factors that resulted in altered level of consciousness.

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ANNEXURE

PATIENT DATA ENTRY FORM

1. Age
2. Sex: a) Male b) Female.
3. In patient no:
4. Date & time of admission:
5. From place of referral
   a)ER b) General ward.
6. Address:

   Phone number:
7. Socio economic status:
8. Developmental delay: a) yes b) no.
9. Any known neurological illness:

   a) yes b) no.

   If yes, type of illness-

   Any treatment taken-
10. Mechanical ventilation: a) yes b) no.

    If yes, reason for intubation-
11. Depressive medication: a) yes b) no.
12. If yes, type of drugs: a) sedatives b) NMB.
13. Date & time of discharge/ death:
14. Duration of hospital stay:

15. Diagnosis:

16. Outcome at discharge: a) death b) discharge.

17. Morbidity in survival at discharge:

a) Normal
b) Symptomatic
c) Slight disability
d) Moderate disability
e) Moderate to severe disability
f) Severe disability
g) Death.

NAME: AGE/SEX; IP.NO;

SCORING SYSTEM

FOUR (The Full Outline of Unresponsiveness) score

		D/	D/	D/	D/	D/	D/	D/	D/	D/	D/	D/
EYE RESPONSE	Eyelids open,tracking,or blinking to command											
	Eyelids open but not tracking											
	Eyelids closed but open to loud voice											
	Eyelids closed but open to pain											
	Eyelids remain closed with pain											
MOTOR RESPONSE	Moves spontaneously/ obeys commands											
	Localizing to pain											
	Flexion response to pain											
	Extension response to pain											
	No response to pain											
BRAINSTEM REFLEXES	Pupil & corneal reflexes present											
	One pupil wide and fixed											
	Pupil or corneal reflexes absent											
	Pupil and corneal reflexes absent											
	Absent pupil, corneal, and cough reflex											
RESPIRATION	Regular breathing pattern											
	Cheyne-stokes breathing pattern											
	Irregular breathing											
	Trigger ventilator or breaths above ventilator rate											
	Apnea/breaths at ventilator rate											
TOTAL SCORE												

INFORMATION SHEET

(To be read to caretakers in the presence of witness)

Your child is admitted in paediatric intensive care unit with altered level of consciousness.

It is a medical emergency. it represents the final pathway of various patho physiological processes in disease states (infections, toxic – metabolic, seizures, vascular, neo plastic & trauma) ultimately leading to derangement in cerebral function manifesting as decreased arousal and awareness.

Prognostication regarding survival and functional outcome of children admitted with altered level of consciousness is a frequent challenge to intensivist. Because of broad range of outcomes, from death to independent functional recovery.

The Glasgow coma is the wildly using tool for predicting outcome of children with altered level of consciousness, but it has number of shortcomings.

The Full outline of unresponsiveness coma score overcomes these shortcomings. It is simple, user friendly, provides far better information, particularly in intubated children.

If we know the accurate predictive validity of this coma scale, it will help us to communicate to a patient's family, regarding the patient's status and what the outcome will be.

How is the study being done?

- If your child admitted in PICU with altered level of consciousness he / she will be recruited based on inclusion and exclusion criteria
- A detailed clinical and neurological examination will be done for all patients.
- Using patient data entry form, information is gathered regarding patients age, sex, other details and scoring system will be measured at admission and then daily till recovery/death.
- Survival and neurologic outcome will be measured.
- Description of the scoring system and interpretation of cut off value for death, squeal, and full recovery etc, will be measured.

Can I refuse to join this study?

You may refuse to participate or withdraw from the study at any time. In both cases your child will be treated in the usual manner in this hospital.

Is there benefit or harm to be in this study?

- By this study we can determine whether the Full outline of Un responsiveness coma scale (FOUR SCORE) is able to predict out come in children with altered level of consciousness.
- If we know the accurate predictive validity of this coma scale, it will help us to communicate to a patient's family, regarding the patient's status and what the outcome will be.
- There are no harms to the patients in this study.

Confidentiality:

The data collected from the study will be used for the purpose of the study only. The results of the study are to be published. Personal information of the children participating in the study will be kept confidential. There will not be any disclosure about your child's information without your permission.

Subjects rights:

I understood that if I wish further information regarding my child's rights as a research subject, I may contact the hospital where the study is taking place.

Consent form

I have been fully informed about the study and the benefits of this study and the possible harm that can happen. I understand that the doctor will ask questions and examine my child to make sure it is safe for him/her to enter the study.

This authorization is valid for this study. “I have understood and received a copy of this consent form”. I agree for my child’s participation in this research study.

Signature / Thumb print of parent or guardian:

Signature of investigator:

Witness signature:

Date:

Principal investigator:

Address:

Phone number:

ABBREVIATIONS

FOUR score	-	Full outline of unresponsiveness score.
GCS	-	Glasgow coma scale.
ARAS	-	Ascending reticular activating system.
ALOC	-	Altered level of consciousness.
MLF	-	Medial longitudinal fasciculus.
RLS (85)	-	Reaction level scale (85).
ED	-	Emergency department.
AVPU	-	Alert/Verbal/Pain responsive and Unresponsive.
ET tube	-	Endotracheal tube.
ICU	-	Intensive Care Unit.
PICU	-	Paediatric Intensive Care Unit.
CNS	-	Central nervous system.
ROC	-	Receiver operating curve.